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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JONATHAN S. STINSON

Appeal 2009-005585
Application 10/721,702[1]
Technology Center 3700

Decided: December 17, 2009

Before SCOTT R. BOALICK, JOHN C. KERINS, and
STEVEN D.A. McCARTHY, *Administrative Patent Judges*.

BOALICK, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Application filed November 25, 2003. Application 10/721,702 is a divisional of U.S. Patent No. 6,652,582, filed October 8, 1999, which is a divisional of U.S. Patent No. 5,980,564, filed August 1, 1997. The real party in interest is Schneider (USA), Inc.

This is an appeal under 35 U.S.C. § 134(a) from the final rejection of claims 30, 44, 46, 50-59 and 76-84. Claims 45 and 47-49 have been withdrawn and claims 1-29, 31-43 and 60-75 have been cancelled. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

Appellant's invention relates to a bioabsorbable implantable medical device formed from a bioabsorbable material. (Spec. Abstract.) The medical device has elongated filaments which include hollow portions to accumulate by-product from the degradation of the bioabsorbable material. (Spec. Abstract.) The medical device can be a stent in which the filaments are helically wound and interwoven into a braided configuration. (Spec. 3:10-12.)

Claims 30 and 82 are exemplary:

> 30. A bioabsorbable endoprosthesis consisting essentially of:
>
> a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer;
>
> wherein the elements occupy a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

82. A bioabsorbable endoprosthesis comprising:

a plurality of elongate elements interbraided into a tubular, radially expandable structure, each of the elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer;

wherein the [sic] each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume;

the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure; and

the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Buscemi	5,500,013	Mar. 19, 1996

Claims 30, 44, 46, 50-59 and 76-84 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over, Buscemi.

Except as noted in this decision, Appellant has not presented any substantive arguments directed separately to the patentability of the dependent claims. In the absence of a separate argument with respect to those claims, they stand or fall with the representative independent claim.

See 37 C.F.R. § 41.37(c)(1)(vii). Only those arguments actually made by Appellant have been considered in this decision. Arguments that Appellant did not make in the Briefs have not been considered and are deemed to be waived. *See id.*

ISSUE

With respect to independent claim 30, Appellant argues that this claim is not anticipated by or obvious over Buscemi because of the transitional phrase "consisting essentially of." (App. Br. 5-11, 14-21.) In particular, Appellant argues that "Buscemi fails to disclose that its stent 10 may consist essentially of fibers 18" because "[t]he main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10." (App. Br. 6; *see also* App. Br. 15, Reply Br. 4-5.) Appellant also argues that the Examiner used impermissible hindsight reconstruction by "pick[ing] and choos[ing] from a reference only so much that supports the alleged rejection" and that "the fibers 18 [are] inoperable as a[n] endoprosthesis when the main body 11 is removed." (App. Br. 16.)

With respect to independent claim 82, Appellant argues that Buscemi does not teach or suggest all the features of this claim. (App. Br. 11-14, 22-25.) In particular, Appellant argues that Buscemi does not teach or suggest that "the number of elements, N, is equal to about (D/(0.022D + 0.17)) ± 4 filaments, where D, in mm, is the free state diameter of the tubular structure" and that "the elongate elements have a thickness, t in mm, of about (D/(1.8D + 15)) ± 0.03 mm, where D, in mm, is the free state diameter

of the tubular structure" because Buscemi is silent as to the relationship of number of filaments and their thickness. (App. Br. 12, 23.) Dependent claim 81, which depends from independent claim 30, recites similar limitations. Appellant also argues that the Examiner used impermissible hindsight reconstruction. (App. Br. 25.)

Appellant's arguments present the following issue:

Has Appellant shown that the Examiner erred in rejecting claims 30, 44, 46, 50-59 and 76-84 under 35 U.S.C. § 102(b), or in the alternative, under 35 U.S.C. § 103(a)?

The resolution of this issue turns on the following subsidiary issues:

1. Has Appellant shown that the Examiner erred in finding that Buscemi teaches or suggests "[a] bioabsorbable endoprosthesis consisting essentially of . . . a plurality of elongate elements," as recited in claim 30?

2. Has Appellant shown that the Examiner erred in finding that Buscemi teaches or suggests that "the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure" and that "the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure," as recited in claim 82?

FINDINGS OF FACT

The record supports the following findings of fact (FF) by a preponderance of the evidence.

Specification

1. Appellant's Specification describes that "[t]he tubular and self-expandable body or structure formed by the interwoven filaments 20, 30, 40 is a primary prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures." (Spec. 18:13-16.) Furthermore, "it is known that other structures and features can be included in stents, and in particular features which enhance or cooperate with the tubular and self-expandable structure." (Spec. 18:16-17.) An example is "the inclusion of a covering . . . to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue ingrowth or be used as a graft." (Spec. 18:20-22.)

Buscemi

2. Buscemi relates to "a device for providing mechanical support and a uniform release of drugs to a vessel lumen of a living being." (Col. 1, ll. 12-14.) Buscemi describes a biodegradable stent 10 (col. 4, ll. 7-8) that "provides mechanical support to a tubular vessel 12 in a living being" (col. 4, ll. 12-14; fig. 1).

3. "The stent 10 includes a generally tubular main body 11 and a plurality of fibers 18 disposed around the main body 11." (Col. 4, ll. 16-18; figs. 1, 2.) As an example, the fibers 18 are formed of poly-L-lactide, a biodegradable material. (Col. 4, ll. 54-56.) The fibers 18 are either solid, hollow or a combination of both (col. 4, ll. 46-47), and, in one embodiment, can be braided or woven around the main body 11 (col. 4, ll. 41-42). The stent 10 also includes a plurality of apertures 14. (Col. 4, l. 18; fig. 1.) The apertures can be "both asymmetrical and symmetrical shapes such as ovals, circles, or rectangles . . . in a variety of sizes." (Col. 5, ll. 41-44.) Such apertures 14 function to "permit[] epithelial cells to grow on the stent 10" (col. 6, ll. 6-7) to encapsulate particles of the stent 10 during biodegradation (col. 6, ll. 7-10).

4. Figures 1 and 3 illustrate an embodiment where "the fibers [18] are arranged concentrically around the main body [11]." (Col. 4, ll. 34-35.) These figures show that there are approximately twenty fibers 18 around the main body 11 in this embodiment. Buscemi is silent as to the number of fibers 18 surrounding the main body 11 in the embodiment where the fibers 18 are braided or woven around the main body 11.

5. The stent 10 has a length from 1 mm to 50 mm and a diameter from 1 mm to 50 mm. (Col. 4, ll. 25-28.) The fibers 18 have an outer diameter not exceeding 0.2 mm (i.e., 200 μm). (Col. 4, ll. 61-62.)

When the fibers 18 are hollow, they have a wall thickness that ranges from 25 to 100 μm. (Col. 4, ll. 62-64.)

PRINCIPLES OF LAW

Anticipation is established when a single prior art reference discloses, expressly or under the principles of inherency, each and every limitation of the claimed invention. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994).

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). In cases involving overlapping ranges, even a slight overlap in range establishes a prima facie case of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). "[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that [the] invention would not have been obvious." *Id.* at 1330.

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). "To facilitate review, this analysis should be made explicit." *KSR*, 550 U.S. at 418.

"By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). To construe the phrase "consisting essentially of," it is "necessary and proper to determine" the interpretation that the Specification reasonably supports. *In re Herz*, 537 F.2d 549, 551 (CCPA 1976). Furthermore, Appellant has the burden of showing that unclaimed limitations in a prior art reference would materially affect the basic and novel characteristics of the claimed invention. *In re De Lajarte*, 337 F.2d 870, 874 (CCPA 1964).

ANALYSIS

We are not persuaded by Appellant's arguments that the Examiner erred in rejecting claims 30, 44, 46, 50-59 and 76-81. However, we agree with Appellant that the Examiner erred in rejecting claims 82-84.

Claims 30, 44, 46, 50-59 and 76-80

Appellant's arguments (App. Br. 7-11, 14-21) that Buscemi does not teach or suggest "[a] bioabsorbable endoprosthesis consisting essentially of . . . a plurality of elongate elements," as recited in independent claim 30, are not persuasive.

The Examiner found that Buscemi teaches all the limitations of independent claim 30. (Ans. 4.) The Examiner further found that the transitional phrase "consisting essentially of" did not exclude the main body 11 of Buscemi because Appellant did not meet the burden of showing

that this unclaimed feature would materially affect the basic and novel properties of the invention. (Ans. 6-7.) We agree with the Examiner.

First, Appellant argues that the basic and novel features of the "inventive stent" are "accelerated degradation achieved by filaments having a reservoir." (App. Br. 9, 19; *see also* Reply Br. 5-6.) However, the stent 10 of Buscemi is presumed to possesses similar "accelerated degradation" properties because it also includes braided or woven hollow fibers 18 formed of a biodegradable material (e.g., poly-L-lactide) (FF 3) with the fibers 18 having an outer diameter of 200 μm and a wall thickness from 25 to 100 μm (i.e., "a reservoir volume" of up to about 56% of the total fiber volume) (FF 5). Appellant has not presented any credible evidence to the contrary.

Next, the Specification describes that "[t]he tubular and self-expandable body . . . formed by the interwoven filaments 20, 30, 40 is a primary prosthetically-functional structure of stent 10, and . . . [this] device can be considered to substantially consist of this structure to the exclusion of other structures." (FF 1.) The Specification also describes that "other structures . . . can be included in stents," and one example is "the inclusion of a covering . . . to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue ingrowth or be used as a graft." (*Id.*) Similar to Appellant's "covering" for stent 10 (*see id.*), Buscemi's main body 11 includes apertures 14 in a variety of shapes and sizes to control cell growth in the stent 10 (FF 3). Because Appellant's Specification indicates that a "covering" for the stent 10 can be included, we conclude that this "covering" does not materially affect the basic and novel characteristics of the claimed bioabsorbable endoprosthesis. Therefore, we do not interpret

the transitional phrase "consisting essentially of" to exclude Buscemi's main body 11.

Furthermore, Appellant's argument that "[t]he main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10" (App. Br. 6; *see also* App. Br. 15, Reply Br. 4-5) is not germane. Appellant has not shown that Buscemi's main body 11 would materially affect the basic and novel characteristics of the claimed bioabsorbable endoprosthesis.

Last, Appellant's arguments that the Examiner used impermissible hindsight reconstruction by "pick[ing] and choos[ing] from a reference only so much that supports the alleged rejection" and that "the fibers 18 [are] inoperable as a[n] endoprosthesis when the main body 11 is removed" (App. Br. 16) are not persuasive. As discussed previously, the transitional phrase "consisting essentially of" does not exclude Buscemi's main body 11. Thus, the rejection is not based upon "pick[ing] and choos[ing]" among the features of Buscemi to exclude the main body 11 or removal of the main body 11 such that the fibers 18 are inoperable as an endoprosthesis.

Therefore, Appellant has not shown that the Examiner erred in finding that Buscemi teaches or suggests "[a] bioabsorbable endoprosthesis consisting essentially of . . . a plurality of elongate elements," as recited in independent claim 30.

We conclude that Appellant has not shown that the Examiner erred in rejecting claim 30 under 35 U.S.C. § 102(b) or in the alternative, under 35 U.S.C. § 103(a). Because Appellant has not presented arguments regarding claims 44, 46, 50-59 and 76-80, we affirm the rejection of these claims

under 35 U.S.C. § 102(b) or in the alternative, under 35 U.S.C. § 103(a) for the same reasons as independent claim 30, from which they depend.

Claims 82-84

Appellant's arguments (App. Br. 11-14, 22-25) that Buscemi does not teach or suggest "the number of elements, N, is equal to about (D/(0.022D + 0.17)) ± 4 filaments, where D, in mm, is the free state diameter of the tubular structure" and "the elongate elements have a thickness, t in mm, of about (D/(1.8D + 15)) ± 0.03 mm, where D, in mm, is the free state diameter of the tubular structure," as recited in independent claim 82, are persuasive.

The Examiner found that Figure 3 of Buscemi illustrates about twenty fibers 18 and that Buscemi teaches that the fibers 18 have an outer diameter of 0.2 mm. (Ans. 7; FF 4.) To satisfy the claim limitation regarding the number of elements, N, the Examiner further found that substituting a diameter of 6 mm for Buscemi's stent 10 (i.e., D = 6) into the claimed formula of "D/(0.022D + 0.17)) ± 4 filaments" produces a result of twenty fibers 18 (or "filaments"). (Ans. 7.) Likewise, to satisfy the claim limitation regarding the element thickness, t, the Examiner found that substituting a diameter of 6 mm for the stent 10 into the claimed formula of "(D/(1.8D + 15)) ± 0.03 mm" produces a result of 0.2 mm. (Ans. 7.)

In the alternative, the Examiner concluded that claim 82 was obvious over Buscemi. (Ans. 6, 7.) The Examiner reasoned that because Buscemi teaches a diameter of the stent 10 ranging from 1 to 50 mm and Figure 3 of Buscemi illustrates about twenty fibers 18, such "overlapping ranges with the formula of the claims . . . is [sic] considered prima facie obvious." (Ans. 6.) Furthermore, the Examiner concluded that such ranges were

obvious for the braided fibers 18 of Buscemi because "engineering choices are made based on optimizing various features including strength." (Ans. 7.) We do not agree.

Figures 1 and 3 of Buscemi illustrate an embodiment where the fibers 18 are arranged concentrically around the main body 11. (FF 4.) However, Buscemi does not teach the number of fibers 18 surrounding the main body 11 in an embodiment where the fibers 18 are braided or woven around the main body (i.e., corresponding to the limitation "a plurality of elongate elements interbraided into a tubular, radially expandable structure"). (*Id.*) Accordingly, the Examiner has not shown that claim 82 is anticipated by Buscemi.

Furthermore, the Examiner has not articulated reasoning with some rational underpinning as to how or why one of ordinary skill in the art would have selected the claimed formulas to optimize particular features when Buscemi is silent as to the number of fibers 18 braided or woven around the main body 11 (FF 4). Accordingly, the Examiner has not shown that claim 82 would have been obvious over Buscemi.

Therefore, Appellant has shown that the Examiner erred in finding that Buscemi teaches or suggests "the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure" and "the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure," as recited in claim 82.

We conclude that Appellant has shown that the Examiner erred in rejecting claim 82 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a). Claims 83 and 84 depend from independent claim 82 and

Appellant has shown error in the rejection of claims 83 and 84 for the reasons discussed above regarding claim 82.

Claim 81

Anticipation Rejection

Appellant has not presented any separate arguments regarding the anticipation rejection of dependent claim 81, which depends from independent claim 30. (App. Br. 11.) Therefore, we affirm the rejection of this claim under 35 U.S.C. § 102(b) for the same reasons as independent claim 30, from which claim 81 depends.

Obviousness Rejection

Appellant's argument (App. Br. 21-22) that Buscemi does not teach or suggest that "the number of elements, N, is equal to about (D/(0.022D + 0.17)) ± 4 filaments, where D, in mm, is the free state diameter of the tubular structure" and "the elongate elements have a thickness, t in mm, of about (D/(1.8D + 15)) ± 0.03 mm, where D, in mm, is the free state diameter of the tubular structure," as recited in dependent claim 81, is not persuasive.

The Examiner found that using a diameter of 6 mm for Buscemi's stent 10 (i.e., D = 6) results in: (1) twenty fibers 18 (or "filaments") for the claimed formula "(D/(0.022D + 0.17)) ± 4 filaments"; and (2) a thickness of 0.2 mm of the fibers 18 for the claimed formula "(D/(1.8D + 15)) ± 0.03 mm." (Ans. 7.) The Examiner concluded that because Buscemi teaches a diameter of the stent 10 ranging from 1 to 50 mm and Figure 3 of Buscemi illustrates about twenty fibers 18, such "overlapping ranges with the formula of the claims . . . is [sic] considered prima facie obvious." (Ans. 6.) We agree with the Examiner because, unlike claim 82, claim 81 does not recite

that the elements are "interbraided into a tubular, radially expandable structure."

Buscemi teaches that the diameter of the stent 10 ranges from 1 mm to 50 mm and that the outer diameter of the fibers 18 does not exceed 0.2 mm. (FF 5.) Buscemi's Figures 1 and 3 also illustrate about twenty fibers 18 surrounding the main body 11. (FF 4.) Because substituting a diameter of 6 mm for Buscemi's stent 10 into the claimed formulas results in overlapping ranges for the number of filaments and the thickness of such filaments, the Examiner has established a prima facie case of obviousness.[2] *See Peterson*, 315 F.3d at 1329. Appellant has not presented any convincing evidence or argument to overcome the prima facie showing.

Moreover, although Appellant argues that the Specification "teaches that a stent of bioabsorbable elements should have similar strength to that of a metallic stent" (App. Br. 21-22) and that the filaments of the stent "should have sufficient strength to hold open a body lumen" (App. Br. 22), these limitations are not claimed.

Therefore, Appellant has not shown that the Examiner erred in finding that Buscemi teaches or suggests that "the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure" and "the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure," as recited in dependent claim 81.

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[2] Again, unlike independent claim 82, which recites "a plurality of elongate elements interbraided into a tubular, radially expandable structure," dependent claim 81 does not recite any specific configuration for the "plurality of elongate elements."

We conclude that Appellant has not shown that the Examiner erred in rejecting dependent claim 81 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a).

CONCLUSION

Based on the findings of fact and analysis above, we conclude that:

(1) Appellant has not shown that the Examiner erred in rejecting claims 30, 44, 46, 50-59 and 76-81 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a).

(2) Appellant has shown that the Examiner erred in rejecting claims 82-84 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a).

DECISION

The rejection of claims 30, 44, 46, 50-59 and 76-81 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), is affirmed.

The rejection of claims 82-84 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

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